K073040

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: SMH BioMaterial AG

DEC 1 3 2007

Date Summary Prepared: 10th October 2007

Contact Persons: Ashley Truitt

Device Name:
Trade Name(s): **SMH Flex "S"**
Classification Name: **Denture resin, relining, repairing or rebasing resin**
Panel: **Dental**
Product Code: **EBI**

Predicate Device Information:

Device Name	Manufacturer	510(k) Reference
Talon & Revere	Comfort Acrylics	K071245
Ivocap Elastomer	Ivoclar Vivodent GmbH	K896130

Device Description:

The submitted device SMH Flex "S" is a pre-mixed acrylic resin for use in the laboratory fabrication of dental prosthesis such as the repair and relining of complete and/or partial dentures, dental appliances including, occlusal splints, night guards, tooth positioners, snoring and sleep apnea devices.

Intended Use:

SMH Flex "S" is intended for the laboratory fabrication of dental prosthesis including the repair and relining of complete and/or partial dentures, occlusal splints, night guards, tooth positioners, snoring and sleep apnea devices, and other appliances as prescribed

Technological Characteristics Compared with Predicate Device
Mechanics, Water Absorption & Solubility, Rest Monomer Concentration, Biocompatibility, Opaque Factor and Density & Consistency.

SMH Flex "S" was also evaluated as follows:

L929 Mem Elution Test – Non Cytotoxic
Intracutaneous Injection Test – Non Irritant
Kligman Maximization Test - Non Sensitivity

Performance Test Data and Conclusions:

We conclude that the similarity in composition between SMH Flex "S" and the predicate devices, as well as the performance data and biocompatibility results, supports the safety and effectiveness of SMH Flex "S" for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

SMH BioMaterial AG
C/O Ms. Ashley Truitt
Consultant
Sonomed, Incorporated
3537 Teasley Lane
Denton, Texas 76210

Re: K073040
Trade/Device Name: SMH Flex "S"
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI and MQC
Dated: October 10, 2007
Received: October 29, 2007

Dear Ms. Truitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

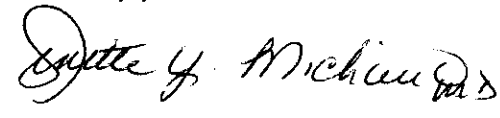
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073040

Device Name: SMH Flex "S"

Indications for Use:

SMH Flex "S" is intended for the laboratory fabrication of dental prosthesis including the repair and relining of complete and/or partial dentures, occlusal splints, night guards, tooth positioners, snoring and sleep apnea devices, and other appliances as prescribed.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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